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From: "Dr. Leo Kadehjian" <drleo@worldnet.att.net>
To: <wvogl@samhsa.gov>
Date: 7/12/04 6:42PM
Subject: Comments on Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing

Dr. Vogl,
Attached please find my comments on the Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing.
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Docket # 04-7984

Walter F. Vogl, Drug Testing Section, Division of Workplace Programs, CSAP

Comments on Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 FR 19673 (April 13, 2004)

Sweat Patch Testing

Dr. Vogl,

First, I wish to take this opportunity to commend HHS and its staff for their exemplary efforts in drafting Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs, availing itself of advances in drug testing technologies to allow more effective drug testing programs.

I am also thankful to have this opportunity to provide my comments to HHS to assist the Department in fulfilling its statutory responsibility to “establish comprehensive standards for all aspects of laboratory drug testing and laboratory procedures to be applied in carrying out Executive order Numbered 12564, ...including standards which require the use of the best available technology for ensuring the full reliability and accuracy of the drug tests ...” Pub. L. 100–71, Title V, § 503 (a)(1)(A)(ii)(I).

My comments herein specifically apply to sweat patch testing. Below I address those sections of the Proposed Rules addressing sweat patch testing on which I wish to comment.

First, I would like to address the Department’s comment that “Sweat patch contamination issues continue to be a concern.” 69 FR 19676. There have been numerous legal challenges to the validity of sweat patch test results based on claims of contamination.

I commend the Department for recognizing “that external absorption of any drugs through the outer layer is not possible under normal circumstances.” 69 FR 19676 This is one basis on which the validity of positive sweat patch test results has been repeatedly challenged. Although the published scientific literature does demonstrate the possibility of permeation of drugs through the sweat patch polyurethane outer membrane in laboratory settings, this has been demonstrated only under unusual laboratory conditions which I believe are not likely to be encountered in a real world setting. A few limited studies claim external contamination during actual patch wear in real life settings but I believe that these studies are not sufficiently robust nor rigorous

to unequivocally support the claims of contamination. In numerous sweat patch cases where I have served as an expert witness I have reviewed the published scientific literature and presented my opinions to the courts, and the courts' rulings have held the challenges to have been insufficient to overcome the demonstrated general reliability of the sweat patch test results.

However, with regards to prior contamination of the skin by drugs leading to subsequent positive sweat patch test results the Department indicated "the Department proposes that the skin area be washed with soap and cool water or with a disposable towelette. Then the collector must thoroughly clean the skin area where the patches will be worn with alcohol wipes prior to application. However, the Department encourages researchers to conduct further research in this area." 69 FR 19677

"With regard to proper cleansing of the skin prior to the application of a sweat patch, the Department is requesting comment on the proposal that the skin area be washed with soap and cool water or with a disposable towelette followed by a thorough cleaning of the skin area where the patches will be worn with alcohol wipes." 69 FR 19687

I wish to point out that such skin contamination from drugs in the environment is not realistic under normal daily circumstances. Although some laboratory experiments have demonstrated increased removal of drug spiked into the skin through a soap and water wash as well as an alcohol wipe, I do not believe that such additional cleaning steps are automatically required to have valid sweat patch test results. I have earlier commented in a report to the federal courts that such an additional soap and water cleaning step appears to be more effective in minimizing the potential for positive test results from any such skin contamination but I wish to make clear that such an additional cleaning step, although providing an additional margin of safety, may not be required.

The experiments demonstrating the possibility of prior skin contamination leading to sweat patch positive test results were performed under what I believe were unrealistic skin contamination conditions not likely to occur in realistic daily settings. In published experiments demonstrating skin contamination from externally applied drug, the subjects' skin were pre-cleaned with alcohol prior to drug impregnation of the stratum corneum from solution. Such alcohol pre-cleaning removes protective oils from the skin as well as rendering the stratum corneum more permeable to applied drugs. Under normal conditions the stratum corneum is one of the most impermeable biological membranes known. When the skin was immediately cleaned with alcohol swabs virtually all applied drug was removed. However when the applied drug in solution as allowed to remain on the skin for several minutes, sufficient drug was spiked into the skin to result in drug detected in subsequently applied sweat patches up to several days thereafter even after normal hygiene and standard skin swabbing prior to sweat patch placement.

Subpart B—Specimens

Section 2.2 Under What Circumstances Can the Different Types of Specimens Be Collected?

I agree with the Department's conclusion that "The sweat patch is best used for return to duty and follow-up testing." 69 FR 19677, 19679 Considering that monitoring of an employee's off-duty behavior may be considered to be highly invasive under 4th Amendment Search and Seizure principles and jurisprudence, it would seem that the use of the sweat patch in federal employee testing should be reserved for "last chance" agreements after a previous drug-related incident.

Section 2.5 What Is the Minimum Quantity of Specimen To Be Collected for Each Type of Specimen?

(c) Sweat: 2 FDA-cleared patches worn up to 7 days

I would like to suggest that although 7 days is a suitable period of patch wear, I do not believe that intact sweat patches which may have been worn for an additional few days are invalid. It should be noted that several published studies involved patch wear for more than seven days. There is no sound scientific basis why a patch worn for more than seven days which was collected intact would not provide valid and accurate results. Although recommending patch wear for up to seven days is sound, an intact sweat patch which happened to be left on for some few additional days should not automatically be considered invalid.

Subpart C—Drug and Validity Tests

Section 3.6 What are the cutoff concentrations for sweat patch samples?

The Department has included a requirement that amphetamine be present at LOD in order for a sweat patch specimen to be reported positive for methamphetamine. 69 FR 19681 This has been the standard practice within the US Federal Courts for some time. The purpose of such requirement within the federal courts sweat patch testing program has been to insure that sweat patch test results comport with those expected from consumption of drug (with metabolite also present) as opposed to results which could be claimed due to external contamination. Although the presence of the metabolite is not necessarily dispositive of the issue (defendants arguing that the externally contaminating drug was not pure but rather also contaminated with some portion of metabolite). In addition the US courts also require that in order for a sweat

patch specimen to be reported positive for cocaine, the patch must also contain benzoylecgonine at LOD. I suggest that the Department consider this additional requirement for cocaine positive specimens. Again although the presence of the metabolite may not be dispositive of the issue, its presence in an appropriate proportion further supports positive sweat patch test results from ingestion rather than unlikely external contamination mechanisms .

Section 3.10 What validity tests must be performed on a sweat patch sample?

(a) For each primary (Patch A) sweat patch sample, an HHS-certified laboratory or IITF must:

(1) Determine the lactic acid concentration on every specimen;

I would suggest that determination of lactic acid offers little benefit to a determination that a sweat patch specimen is valid. Trained collectors can observe if a sweat patch has been tampered with. As the Department noted in its discussion of sweat patch testing, "Attempts to remove or tamper with the FDA-cleared sweat patch are usually visible to personnel trained to remove them"

Subpart H—Specimen Collection Procedure

Section 8.4 What procedure is used to collect a sweat patch sample?

(a) The collector must use the following procedure to collect a sweat patch sample:

(5) The collector asks the donor to thoroughly clean the skin area with soap and cool water or with a disposable towelette and then the collector must thoroughly clean the

skin area with alcohol wipes where the sweat patches will be worn prior to application.

Although limited experimental skin doping studies indicate that such a soap and water wash prior to the an alcohol swabbing of the area to which the patch is to be applied may provide greater assurance that the effects of any potential residual drug in the skin may be minimized, I do not believe that such an additional cleansing procedure is required in order to have valid sweat patch test results. In experiments where skin was artificially doped with drug, an additional soap and water wash did offer additional protection from positive sweat patch test results. However I believe that such artificial skin doping experiments do not represent conditions likely to be encountered in practical daily real life scenarios.

(7) The donor must wear the sweat patches for no less than three and no more than seven days before returning to the collection site.

Regarding the proposed requirement “that the patch be worn at least 3 days but no more than 7 days” 69 FR 19680, 19687 I wish to point out that several published studies involved patch wear for more than seven days. There is no sound scientific basis why a patch worn for more than seven days which was collected intact would not provide valid and accurate results. Although recommending patch wear for up to seven days is sound, an intact sweat patch which happened to be left on for some few additional days should not automatically be considered invalid.

I again thank the Department for this opportunity to provide information to assist it in drafting and finalizing drug testing guidelines and for their careful consideration of these points. I am eager to offer whatever further information and comments to the Department that will allow it to fulfill its statutory obligations to “establish comprehensive standards for all aspects of laboratory drug testing and laboratory procedures to be applied in carrying out Executive order Numbered 12564, ...including standards which require the use of the best available technology for ensuring the full reliability and accuracy of the drug tests ...”

Sincerely,

A handwritten signature in black ink that reads "Leo Kadehjian". The signature is written in a cursive, slightly slanted style.

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